510(k) SUMMARY K072647

Applicant	BioFilm, Inc. 3225 Executive Ridge Vista, CA 92081
Contact Person	Robert L. De Armond V.P. Operations / Regulatory Affairs (760)727-9030 Phone (760)477-2424 Fax
Date Prepared	September 11, 2007
Proprietary Name	Glycerin & Paraben Free Astroglide®
Common Name	Personal Lubricant
Classification Name	HIS - Condom, (21 CFR 884.5300) MMS - Patient Lubricant (21 CFR 880.6375)
Predicate Device	Good Lubrications Personal Lubricant (K020586)

JAN 25

Description of Device

Glycerin & Paraben Free Astroglide® is a non-sterile, clear, non-greasy, high viscosity liquid used as a personal lubricant. Glycerin & Paraben Free Astroglide® is not a contraceptive or spermicide. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according the standards defined by ASTM D 3492.

Indications for Use

Glycerin and Paraben Free Astroglide® is a personal lubricant, for penile, anal, or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

This product is compatible with latex condoms.

Technological Characteristics

Glycerin & Paraben Free Astroglide® formula is proprietary. The product however has no exceptional technological characteristics consisting mainly of water soluble ingredients similar to other lubricants currently on the market.

Substantial Equivalence

This product has been shown in laboratory testing to be substantially equivalent to the currently marketed Good Lubrications Personal Lubricant (K020586) and Astroglide Personal Lubricant (K935299). Both devices have the same intended use and similar formulation.

510(k) SUMMARY

Product Testing per ISO 10993

Biocompatibility studies on Glycerin & Paraben Free Astroglide® conducted by outside laboratories, in compliance with Good Laboratory Practices (GLP's) demonstrated:

- in a Dermal Sensitization Study that the product was considered to be a Grade I (weak) sensitizer in guinea pigs. (ISO 10993-10)

- in a 5-Day Rabbit Penile Irritation Study that the product was considered to be a minimal irritant as compared to the control article, 0.9% NaCL. (ISO 10993-10)

- in a 5-Day Rabbit Vaginal Irritation Study that the product was considered to be a nonirritant as compared to the control article, 0.9% NaCL. (ISO 10993-10)

- in a Mouse Systemic Injection Study that the product did not cause mortality and was not associated with systemic toxicity. (ISO 10993-11)

- in a 50 human subject Repeat Insult Patch Test that the product may be considered as a Non-Primary Irritant and Non-Primary Sensitizer.

- in a test for Cytotoxicity at a dilution of 1:4 or greater that the product satisfied the requirements of a ISO MEM Elution Test and passed the test. (ISO 10993-5)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 25 2008

Mr. Robert L. De Armond
Vice President Operations/Regulatory Affairs
BioFilm, Inc.
3225 Executive Ridge
VISTA CA 92081

Re: K072647
Trade/Device Name: Glycerin & Paraben Free Astroglide
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 4, 2007
Received: December 10, 2007

Dear Mr. De Armond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072647

Device Name: Glycerin & Paraben Free Astroglide®

Indications For Use:

Glycerin and Paraben Free Astroglide® is a personal lubricant, for penile, anal, or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

This product is compatible with latex condoms.

Prescription Use _____ AND/OR Over-The Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072647